

## **REMARKS**

In the Office Action issued on June 30, 2008, the Examiner:  
made the previously issued restriction requirement final;  
rejected Claims 36 and 37 under 35 U.S.C. §102(a) as being anticipated by  
United States Patent Application Publication No. 2003/0023303 (Palmaz).

The Applicants have fully considered the Office Action and cited reference  
and submit this Reply and Amendment in response to the Examiner's action.  
Reconsideration of the application for patent is requested.

### Amendments to the claims

The Applicants have herein canceled claim 36. The rejection of this claim is,  
therefore, moot.

The Applicants have herein amended independent claim 37 to more  
particularly point out and distinctly claim that which the Applicants regard as their  
invention for this particular claim. Specifically, claim 37 has been amended to  
clarify the location and structure of the imageable structure and to further clarify  
the steps of imaging the delivery apparatus and determining the orientation of  
the orifice. Additional amendments relating to typographical and other clerical  
errors have also been made.

All of the amendments to claim 37 are fully supported by the application as  
originally filed; no new matter has been introduced. Exemplary support is found  
in paragraphs [0056], [0057], and [0058], and in Figures 20, 21, and 23.

### Rejections under 35 U.S.C. §102

The Examiner rejected Claims 36 and 37 under 35 U.S.C. §102(a) as being  
anticipated by Palmaz (US 20030023303).

The applicants have herein canceled claim 36. The rejection of this claim is,  
therefore, moot and should be withdrawn.

As amended herein, independent claim 37 specifically requires:

- an imageable structure comprising first and second imageable elements located about the first and second ends of the orifice
- a step of imaging the delivery apparatus and the valve prosthesis using an external imaging system to determine a location of the imageable structure relative to at least one of the valve prosthesis and the delivery apparatus;
- a step of determining the orientation of the orifice within the delivery apparatus relative to at least one of the valve prosthesis and the delivery apparatus using the determined location of the imageable structure; and
- a step of verifying that the determined orientation of the orifice is indicative of a delivery approach specified by indicia located on at least one of the delivery apparatus, the valve prosthesis, and the packaging material thereof; wherein a determined orientation in which the orifice of the valve prosthesis is located closest to the distal end of the delivery apparatus is indicative of an ascending delivery approach, and wherein a determined orientation in which an end of the valve prosthesis that is opposite the orifice of the valve prosthesis is located closest to the distal end of the delivery apparatus is indicative of a descending delivery approach.

Palmaz does not anticipate claim 37 at least because the reference does not teach or suggest a step of verifying that the determined orientation of the orifice is indicative of a delivery approach specified by indicia located on at least one of the delivery apparatus, the valve prosthesis, and the packaging material thereof. Indeed, Palmaz is completely devoid of any teaching or suggestion of an indicia relating to a delivery approach for the delivery apparatus, let alone a step of

verifying that a determined orientation of the orifice is indicative of a delivery approach specified by such indicia.

Accordingly, Palmaz does not explicitly anticipate claim 37 under 35 U.S.C. §102 because it does not teach each and every limitation of the claim.

Furthermore, Palmaz does not anticipate the claimed method under the principles of inherency because the prior art device would not necessarily perform the claimed method as amended herein. Indeed, the prior art device is incapable of performing the claimed method because the radiopaque markers are described as being provided on the stent body relative to an opening defined by the stent, i.e., an opening defined by the elimination of a strut of the stent. As described by Palmaz:

“...[T]he proximal anchor flange 22...is configured to have one or more stent struts eliminated from the proximal anchor flange to define an open region....In the case of providing an oriented opening in the proximal anchor flange...it is desirable to provide radiopaque markers on the stent body member 12 to permit the CV valve stent to be oriented correctly relative to the anatomic structure.”

Palmaz, paragraphs [0078] and [0080]

Thus, Palmaz describes a stent that can include radiopaque markers on the stent body that are adapted to permit orientation of an opening in the stent structure. The reference does not teach or suggest a step of determining an orientation of a valve orifice using the location of an imageable structure on a valve prosthesis. Also, as described above, the reference certainly does not teach or suggest a step of verifying that a determined orientation of a valve orifice is indicative of a delivery approach specified by indicia located on at least one of the delivery apparatus, the valve prosthesis, and the packaging material thereof. Accordingly, it cannot properly be said that the Palmaz prior art device would *necessarily* perform the claimed method.

Lastly, the Applicants note that the Palmaz prior art device does not inherently disclose claim 37, prior to the amendments made herein, because the device would not necessarily perform the method of unamended claim 37 at least because the reference does not teach or suggest a step of determining an orientation of a valve orifice using the location of an imageable structure on a valve prosthesis.

The Applicants respectfully assert that the rejection based on Palmaz has been overcome and request its withdrawal.

## **CONCLUSION**

The Applicants have fully responded to the objections and rejections listed by the Examiner in the June 30, 2008, Office Action. A Notice of Allowability relating to all claims currently under consideration is appropriate and respectfully requested by the Applicants.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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